

K193659 iTero Element 5DMar 20, 2020
81 days to decisionK193659 · Product code: **NTK** · Dental
Source: <https://www.510kdatabase.net/k193659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Caries Detector, Laser Light, Transmission (NTK)
Date received	Dec 30, 2019
Decision date	Mar 20, 2020
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Align Technology, Inc.
Location	San Jose, CA, US
Contact	Angela M. Frederickson
510(k) history	11 submissions · 11 cleared · 2015-2025

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